UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	No.
	)	
v.	)	
	)	
MED PREP CONSULTING, INC., a corporation, and GERALD R. TIGHE, an individual,	)	COMPLAINT
	)	
	)	
	)	
	)	
Defendants.	)	
	)	

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Med Prep Consulting, Inc. ("Med Prep"), a corporation, and Gerald R. Tighe, an individual (collectively, "Defendants"), from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(1), 351(a)(2)(A), and/or 351(a)(2)(B) and/or misbranded under 21 U.S.C. § 352(j); (b) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(1), 351(a)(2)(A) and/or 351(a)(2)(B) and/or misbranded under 21 U.S.C. § 352(j); and (c) violating 21 U.S.C. § 331(d) by introducing

or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) & (c).

Defendants

4. Med Prep was incorporated in New Jersey in 1994, and its corporate headquarters are located at 1540 West Park Avenue, Suite 5, Tinton Falls, New Jersey 07712. Med Prep is licensed by the State of New Jersey. During the regular course of business, Med Prep manufactures, repackages, processes, packs, labels, holds and/or distributes articles of drug within the meaning of 21 U.S.C. § 321(g)(1). Med Prep's drug products include, but are not limited to, pain management medications, anesthesia and operating room drugs, and oncology and dialysis drugs.

5. Gerald R. Tighe is Med Prep's President and Owner. He is responsible for and oversees all aspects of Med Prep's business, including, but not limited to, manufacturing and quality operations. As President, Mr. Tighe is the highest ranking corporate official and most responsible person at Med Prep. Mr. Tighe performs his duties at 1540 West Park Avenue, Suite 5, Tinton Falls, New Jersey 07712, within the jurisdiction of this Court.

Defendants' Operations

6. Defendants manufacture sterile drug products for approximately 70 hospitals and health care facilities on a contractual basis.

7. Defendants manufacture sterile drugs, including, but not limited to, sufentanil with bupivacaine, fentanyl citrate with bupivacaine hydrochloride, heparin 5000 units in 1000 ml 0.9% sodium chloride, vancomycin 1 gram in 250 ml 0.9% normal saline, magnesium sulfate and dexamethasone 20 mg in 50 mL 0.9% sodium chloride.

8. Defendants repackage numerous sterile drugs, including granisetron syringes and leukine syringes.

9. Many of Defendants' drug products are intended to be injected into the vascular systems of patients. Nonsterility, bacterial endotoxin contamination, errors in strength of correct components, and incorrect components in sterile drug products are especially dangerous when the drugs are administered into the vascular and/or central nervous systems.

10. Defendants distribute their drugs without receiving a valid prescription for an identified individual patient.

11. Defendants have been engaged in manufacturing, repackaging, processing, packing, labeling, holding, and distributing drugs in interstate commerce. Defendants distribute drugs in interstate commerce to states outside of New Jersey, including Connecticut.

12. Defendants manufacture drugs using components they receive in interstate commerce. For example, FDA has determined the magnesium sulfate for injection and aztreonam for intravenous use that are used by Defendants are not manufactured by any pharmaceutical manufacturing facilities in New Jersey registered with FDA. Therefore, these drug components have traveled in interstate commerce.

Requirements of the Act

13. A drug is deemed to be misbranded if "it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j).

14. A drug is deemed to be adulterated if it "consists in whole or in part of any filthy, putrid, or decomposed substance." 21 U.S.C. § 351(a)(1).

15. A drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions . . . whereby it might have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

16. The Act requires that drugs be manufactured in accordance with Current Good Manufacturing Practices ("CGMP"). 21 U.S.C. § 351(a)(2)(B). Under the Act, a drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its preparation do not comply with CGMP to assure that it meets the requirements of the Act as to its safety and that it has the identity and strength, and meet the quality and purity characteristics, which it purports or is represented to possess, regardless of whether the drug is actually defective in some way. FDA has promulgated CGMP regulations for drugs. 21 C.F.R. Parts 210, 211.

17. The Act further requires, subject to certain exceptions not applicable here, that drug manufacturers obtain FDA approval of a new drug application ("NDA") or abbreviated new drug application ("ANDA") with respect to any new drug they introduce into interstate commerce. 21 U.S.C. §§ 331(d), 355(a). A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21

U.S.C. § 321(p)(1). A compounded drug is a "new drug" under the Act. *Medical Center Pharmacy v. Mukasey*, 536 F.3d 383, 393-94 (5th Cir. 2008).

Defendants' Violations of the Act

18. On or about March 13, 2013, Defendants received notice from one of their customers that floating particles were observed in a magnesium sulfate injectable drug product that was labeled as sterile. Further investigation revealed that there were three distinct lots of magnesium sulfate drug product distributed by Defendants that contained visible contamination. Subsequent laboratory analysis by Defendants' third-party laboratory revealed that the floating particles in these lots were actually mold. In response, Med Prep voluntarily recalled all lots of all products that it distributed through March 13, 2013.

19. FDA investigators collected samples of two of the three lots of Defendants' visibly contaminated magnesium sulfate drug product from Defendants' customer. FDA's Northeastern Regional Laboratory analyzed those samples and confirmed the presence of microbiological contamination in both of those lots.

20. In response to reports of visibly contaminated injectable drug products, FDA inspected Med Prep's facility between March 15 and April 3, 2013 ("March 2013 inspection"). During that inspection, FDA investigators observed and documented insanitary conditions and numerous violations of CGMP. During the inspection, FDA investigators also collected samples of some of Defendants' drug products from Defendants' facility.

21. FDA's Northeastern Regional Laboratory analyzed the samples collected by FDA investigators during the inspection of Med Prep and found microbiological contamination in another lot of Defendants' magnesium sulfate drug product. This lot of magnesium sulfate is

distinct from the two lots that had been previously been confirmed by FDA analysis to contain microbiological contamination.

22. Additional FDA testing of the three lots of magnesium sulfate that had contained mold revealed that they were subpotent, containing 78.5%, 82.3%, and 77.0% of the labeled amount of active ingredient. A fourth lot of magnesium sulfate injectable drug product was tested and also found to be subpotent, containing 76.1% of the labeled potency. Each of these lots should have contained between 93.0% and 107.0% of the amount of active ingredient stated on the product label.

23. Following FDA's inspection, Defendants' third-party laboratory analyzed a lot of another of Defendants' products, dexamethasone 8 mg/50 ml 0.9% Normal Saline, and determined that that product also contained mold.

24. On March 15, 2013, Med Prep entered into a voluntary agreement with the State of New Jersey to temporarily cease operations. That agreement was extended until April 12, 2013. On April 12 and 15, 2013, the New Jersey State Board of Pharmacy held a hearing. The result of that hearing was that Med Prep would be permitted to resume operations once it met certain conditions and made a submission to the Board of Pharmacy. On May 6, 2013, Med Prep's attorney informed FDA that Med Prep intended to resume operations that same week, if permitted by the State of New Jersey, but, upon information and belief, Defendants have not resumed operations

Dangerous to Health

25. As alleged above in paragraphs 18-19, Defendants distributed purportedly sterile drug products that were later observed to contain visible mold. Such drug products are dangerous to health because they introduce virulent organisms directly into the bloodstream

when used in the dosage or manner prescribed, recommended, or suggested in the labeling thereof. Such organisms can result in fever, chills, shock, endocarditis, brain abscess, and/or endophthalmitis. Because the mold renders these drugs dangerous to health, they are misbranded under 21 U.S.C. § 352(j).

26. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(j), in that they are dangerous to health when used in the dosage or manner prescribed, recommended, or suggested in the labeling thereof.

27. Defendants also violate 21 U.S.C. § 331(k) by causing the misbranding, within the meaning of 21 U.S.C. § 352(j), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Filth

28. Defendants distributed purportedly sterile drug products that were later found to contain visible mold as alleged in paragraphs 18-19 above.

29. Any microbiological contamination in a purportedly sterile drug product is filth within the meaning of the Act.

30. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(1), in that they consist in whole or in part of any filthy, putrid, or decomposed substance.

31. Defendants also violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(1), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Insanitary Conditions

32. Actual fungal contamination of multiple lots of Defendants' purportedly sterile injectable drug products, and conditions observed in the Med Prep facility by FDA investigators during the March 2013 inspection, establish that all drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A).

33. As discussed in paragraphs 18-19, in March 2013, Med Prep became aware that multiple bags of its magnesium sulfate injectable drug products that were labeled as sterile actually contained mold, which is microbiological contamination.

34. Microbiological contamination of multiple lots of a purportedly sterile drug product is strong evidence that Defendants' drug products were held under insanitary conditions whereby they could have been rendered injurious to health.

35. During the March 2013 inspection, FDA documented insanitary conditions, including but not limited to the following:

a. Med Prep's environmental test results reveal microbial contamination in samples collected from, among other things, employee gloves, and gowns in Med Prep's clean room. Analyses of samples collected in Defendants' clean room between 2011 and 2013 reveals the documented presence of bacteria and fungus.

b. FDA investigators documented insanitary employee practices in the clean room, including, but not limited to, wearing clothing inappropriate and insufficient for the duties they perform. This includes use of non-sterile and non-protective clothing and having exposed areas of employees' skin.

c. MedPrep's cleaning practices of equipment and utensils are insufficient to prevent contamination. Sanitization and/or sterilization of these items are not conducted at appropriate intervals.

d. Med Prep's aseptic processing environment is not designed to prevent microbial contamination from entering the clean room. At Med Prep, the flow of material, equipment, and staff from other rooms flows directly into the clean room without going through an appropriate intermediate environment. Additionally, the movement of people within the clean room may alter the airflow and the quality of the air in the clean room. Such building design creates a risk of contamination in the clean room.

36. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they are prepared, packed, or held under insanitary conditions whereby they might have been rendered injurious to health.

37. Defendants also violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(A), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Deviations from CGMP

38. During the March 2013 inspection, the FDA investigators documented numerous deviations from CGMP. These observations establish that all drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B). The CGMP violations included, but were not limited to, the following:

a. Failure to establish procedures to prevent microbiological contamination of drug products purporting to be sterile. *See* 21 C.F.R. § 211.113(b);

b. Failure to clean, maintain equipment and utensils, and, as appropriate for the nature of the drug, sanitize and/or sterilize at appropriate intervals to prevent malfunctions or contamination that would alter or destroy the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements. *See* 21 C.F.R. § 211.67(a);

c. Failure to conduct appropriate laboratory testing on each batch of drug product purporting to be sterile and/or pyrogen-free to determine conformance to such requirements. *See* 21 C.F.R. § 211.167(a);

d. Failure of personnel engaged in the manufacture, processing, packing or holding of a drug product to wear clean clothing appropriate for the duties they perform, and to wear, as necessary, protective apparel, such as head, face, hand, and arm coverings, to protect drug products from contamination. *See* 21 C.F.R. § 211.28(a); and

e. Failure to thoroughly review and investigate any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications for distributed finished drug products. *See* 21 C.F.R. § 211.192.

39. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their preparation do not comply with CGMP, to assure that they meet the requirements of the Act as to their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

40. Defendants also violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Unapproved New Drugs

41. During FDA's most recent inspection, FDA investigators observed that Defendants market numerous drug products, including, but not limited to magnesium sulfate, 2 grams in 50 mL 5% dextrose; morphine, 4 mg/mL; atropine injection, 0.4 mg in 1 mL; oxytocin 20 units added to lactated ringers 100 mL; vancomycin HCl added to 250 mL 0.9% sodium chloride; dexamethasone 20 mg in 50 mL 0.9% sodium chloride. Those drug products lack an approved new drug application or approved abbreviated new drug application, as required by 21 U.S.C. § 355, and are not exempt from approval.

42. Defendants' drug products, including but not limited to magnesium sulfate, 2 grams in 50 mL 5% dextrose; morphine, 4 mg/mL; atropine injection, 0.4 mg in 1 mL; oxytocin 20 units added to lactated ringers 100 mL; vancomycin HCl added to 250 mL 0.9% sodium chloride; dexamethasone 20 mg in 50 mL 0.9% sodium chloride are not generally recognized as safe and effective because there are no published adequate and well-controlled clinical studies of those drugs manufactured and distributed by Med Prep for any indication. Therefore, they are new drugs within the meaning of 21 U.S.C. § 321(p).

43. Because Defendants' drugs lack an approved new drug application or approved abbreviated new drug application, as required by 21 U.S.C. § 355, and are not exempt from approval, Defendants' distribution of their unapproved drugs into interstate commerce violates 21 U.S.C. § 331(d).

Prior Notice and History of Non-Compliance

44. Defendants have a history of failing to comply with the Act. After a December 2009 inspection, FDA sent Defendants a Warning Letter informing them that, based on the repackaging operations they performed, Defendants were obligated to comply with CGMP, 21

U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210, 211, and register with FDA as a manufacturer. *See* 21 U.S.C. § 352(o). Defendants and FDA exchanged numerous communications and met in February 2011 to discuss Defendants' non-compliance. FDA investigators observed during the 2013 inspection that, despite such notice, Defendants continue repackaging drugs in violation of the Act's CGMP and premarket approval requirement for new drugs.

45. Despite these warnings, Defendants' violations have persisted, as shown by the continued violations observed during the 2013 inspection of the Med Prep facility. Plaintiff is informed and believes that, unless restrained by this Court, Defendants will continue to violate 21 U.S.C. § 331(a), (d), and (k), in the manner alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them from manufacturing, repackaging, processing, packing, labeling, holding, or distributing any article of drug, unless and until Defendants bring their manufacturing, repackaging, processing, packing, labeling, holding, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of FDA;

II. Permanently restrain and enjoin Defendants Med Prep Consulting, Inc., Gerald R. Tighe, and each and all of their officers, agents, employees, successors or assigns, representatives, and attorneys, and any and all persons in active concert or participation with any of them, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(j);

B. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(j);

C. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(1), 351(a)(2)(A), and/or 351(a)(2)(B);

D. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(1), 351(a)(2)(A), and/or 351(a)(2)(B);

E. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355, nor exempt from approval.

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, repackaging, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and other such relief as the Court deems just and proper.

DATED this 21st day of June, 2013.

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